SUMMARY OF THE
ON-SITE ASSESSMENT COMMITTEE MEETING
JUNE 27, 2000

The On-site Assessment Committee of the National Environmental Laboratory Accreditation Conference (NELAC) met on Tuesday, June 27, 2000 at 9 a.m. Eastern Daylight Time (EDT) and 1:30 p.m. as part of the Sixth NELAC Annual Meeting in Williamsburg, VA. The meeting was led for the first half of the meeting by its chair, Mr. William Ingersoll of the U.S. Navy, and for the second half of the meeting by Mr. R. Wayne Davis of the South Carolina Department of Health and Environmental Control. A list of action items is given in Attachment A. A list of participants is given in Attachment B. *The purposes of the meeting were to review the pilot basic assessor training course and standard, the proposed technical training standards, the committee's issue paper on the scope of the on-site assessment, and the committee's proposed changes to the NELAC On-site Assessment Standard.*

INTRODUCTION

Following a welcome and a review of the ground rules by the session's facilitator, Mr. Owen Crankshaw, committee members introduced themselves. Mr. Ingersoll then moved to the first item on the committee agenda that had been distributed in meeting packets.

REVIEW OF PILOT BASIC ASSESSOR TRAINING COURSE AND STANDARD

Ms. Marlene Moore led a review of the pilot assessor training course presented in Maryland and California in March 2000. The purpose of the pilot course was to assure that assessors from the first approved Accrediting Authorities had some form of assessor training and had read the NELAC Quality Systems (QS) Standard. In addition to at least one assessor representative from ten of the then twelve Accrediting Authorities, representatives from some other states, the U.S. Environmental Protection Agency (EPA), and the Department of Defense (DOD) attended the training course. Course training materials were provided by EPA and reviewed by the On-site Assessment Committee. Eleven third-party instructors participated. Eighty-one graduates attended all five course days, completed an examination administered at the conclusion of the course, and received a certificate for successful completion of the course. Attendees provided input via a form for course feedback and an evaluation form.

Ms. Moore noted that the On-site Assessment Committee had wanted to ensure that basic assessor training would be consistent. To that end, instructors adhered to the specific statements in the instructor's manual during the first two days of the course. By the third day of the course, however, the prescriptive nature of the instructor's manual had proved cumbersome. In the Maryland course, instructors trained by the QS checklist. They found that there was no way to cover every item on checklist in the time allowed. Attendees were asked to review the Standard and provide written questions so that instructors could concentrate on those areas of the Standard. Instructors took their Maryland course experience into the California course offering. Consequently, they rearranged the order in which some of the training manual chapters were offered and trained by the Standard rather

than the checklist. Although the resulting California course was presented more effectively, attendees still provided comments for improvement. Attendees suggested more group exercises, such as completely walking through the writing of a deficiency report.

Ms. Moore noted that Dr. Ken Jackson of the New York Department of Health will chair a subcommittee to revise the course materials in response to comments received and experience gained in the administration of the pilot training course. Dr. Margo Hunt of EPA will also serve on the subcommittee. At the invitation of the committee, Dr. Jackson provided his comments on the pilot training course. He suggested that the basic content is fine but that the instructor's manual is too prescriptive. He also suggested that the course could be shortened. Dr. Jackson anticipated that it would take only a few months to revise the course materials.

Ms. Moore noted that, unexpectedly, none of the assessors attending the pilot course had ever attended a NELAC meeting. She also noted the beneficial nature of sharing information and recognizing commonalities among the course attendees. For these reasons, she encouraged an annual refresher course. Ms. Moore recognized the stakeholders whose input had helped shape the course and the instructors who had donated their time.

The committee noted that the revised course will be included as a basic training standard in the proposed Appendix A to the NELAC On-site Assessment Standard (Chapter 3). A second proposed appendix, Appendix B, will constitute the technical training standards.

TECHNICAL TRAINING STANDARDS

Mr. Jack Hall led a review of the proposed Appendix B. Mr. Hall addressed the committee's discussion of how they would develop technical training courses and acknowledged that the committee had come to the conclusion that they are not equipped to handle the approval of technical training courses. There are several existing technical training courses that with minor revision may fulfill the needs of NELAC assessor technical training. It is the responsibility of each Accrediting Authority to make sure that its assessors are trained to meet the requirements of NELAC. The technical training courses assume some level of basic knowledge in the course subject. Appendix B will emphasize the criteria specified in the Standard and is divided into two main sections addressing QS and the principles of the methods.

Mr. David Friedman offered an alternative approach to technical training. He suggested that technical training focus on what the assessor needs to know about a given technology rather than focus on the technology as if teaching someone to perform the analysis. The syllabus for such a course would cover how to:

- evaluate the acceptability of analyst training and experience,
- evaluate instrumentation calibration procedures,
- evaluate laboratory procedures for verifying the suitability of methods and laboratory Standard Operating Procedures (SOPs),

- verify that the laboratory is maintaining instrument calibration on a continuing basis,
- verify that the laboratory is documenting that the measuring methods are correct (bias, precision, etc), and
- examine a QS packet to document that the laboratory Quality Management system is being correctly applied to the methods used by the laboratory.

The committee then opened the assessor training issue for discussion from the floor. There was considerable discussion of technical training, particularly of what constitutes technical competence for assessors and of the consistent interpretation and application of the NELAC Standards. A commenter experienced in drinking water analysis noted that EPA Region 10 requires that assessors for drinking water laboratories be hands-on analysts. Noting that the proposed training appears to be geared toward chemists, the commenter urged the committee to include emerging microbiology technologies. Committee members acknowledged that they have wrestled with the issue of whether technical competence alone is enough to ensure a good assessor and asked whether there is a need for both technical training and assessment training approaches. Commenters were generally of the opinion that it does not work to have non-technical personnel perform technical assessments and that technical training is no substitute for hands-on experience. There was some discussion of an assessment team approach in which some team members would possess a working knowledge of current and ongoing technology and other team members would possess a working knowledge of Quality Assurance (QA) auditing and the peripheral areas of data management, personnel training, etc. In response to the committee question of whether it is necessary to add to the Standard an explicit requirement that assessors be technically competent in their subject technical discipline, it was suggested that the requirement is already implicit.

It was suggested that the committee is sidestepping the issue of approval of training courses. In response, the committee noted that as a standard-setting body they will set the criteria for training courses and the training vendors will produce the training materials geared to assessors for approval by the Accrediting Authorities. It was suggested that the committee consider approaching EPA for assistance from individuals within the drinking water laboratory certification program, many of whom are nearing retirement and might be willing to help with setting technical training criteria.

It was suggested by a commenter from a company with offices in several states that the committee include a provision to ensure the consistent application of the NELAC QS Standard among different Accrediting Authorities. In discussion of this issue, commenters generally supported some kind of annual refresher course to address ambiguities of language or common misinterpretations of the NELAC Standards. It was noted that the use of the word “course” implies the use of a syllabus, instructor manual, student training manuals, etc. and suggested that a “forum” or “workgroup” would be more appropriate and less prescriptive. It was generally agreed that NELAC assessors should gather at regular intervals to discuss common misinterpretations of the Standard and that the outcome of these forums should be posted on the NELAC Website for public access. In further discussion of the issue, it was noted that the Standard must be clearly written and that requests for interpretations of ambiguous language should be submitted to the relevant Accrediting Authority. There was some discussion of how

Accrediting Authorities are documenting their interpretations and of the process for resolving complaints. It was noted that there is no input body for assessed laboratories and this may be considered a problem with the program. It was suggested that a downloadable form with which to request interpretation of the Standard be included on the NELAC Website and that a compilation of answers be posted periodically for guidance. The committee deemed this an issue for the Quality Systems Committee. The committee suggested the global removal of the word "course" from the On-site Assessment Standard. A commenter noted that there are organizations that evaluate courses and grant Continuing Education Units (CEUs) and that he had provided the committee with a packet of information from one such organization.

ON-SITE ASSESSMENT ISSUE PAPER

Mr. Davis presented an issue paper distributed by the committee prior to the meeting. He noted that the paper had been prepared to address two main issues:

- Should laboratory assessors review every test within a laboratory's scope of accreditation, or only representative tests, as suggested in the proposed changes to the Standard?
- How do laboratory assessors establish at the bench level that laboratory SOPs are actually being implemented and applied?

Mr. Davis suggested that the resolution of these issues is critical to the ultimate success of NELAC. He pointed out a misnomer in the reference to the paper in the committee's published agenda. The paper is not an opinion paper because it does not represent the consensus opinion of the committee. Rather, the paper presents one suggested approach for ensuring that the scope of the assessment is such that the assessor is comfortable that each method is being performed correctly at an assessed laboratory. After briefly reviewing the paper, Mr. Davis solicited input from the floor. Reaction from the floor was somewhat mixed. A commenter with radiochemistry experience suggested that it would be impossible to review every test within a radiochemistry laboratory's scope of accreditation within a reasonable period of time. After reviewing the NELAC Glossary definition for "test," a committee member suggested that the committee had been misusing the word "test" and suggested substituting "scope of accreditation" for "all of the tests" in Section 3.4.2 of the Standard. This generated discussion of scope of accreditation. The committee noted that a concurrent special session was being held to address "scope of accreditation" issues and that such a language change simply points readers to the outcome of that special session.

PROPOSED CHANGES TO CHAPTER 3

Mr. Ingersoll and Mr. Davis led a review of and solicited feedback from the floor on each of the committee's proposed changes to the Standard. The committee made additional minor editorial changes where necessary to correct typographical errors in the published proposed changes, and globally removed the word "course" from the Standard in keeping with their earlier discussion of technical training. Many of the proposed changes met with only minimal discussion from the floor. Sections generating more substantial discussion are summarized below.

- Section 3.2.1 (Basic Qualifications) - Additional discussion of technical training for assessors ensued. It was suggested that the use of the phrase "working knowledge" in item "e" implicitly requires technical experience. A commenter asked by what mechanism an Accrediting Authority can verify working knowledge. In response, the committee noted that the Standard requires four items:
  - training in the NELAC Standard (to be obtained within two years)
  - training in how to conduct a laboratory assessment
  - technical training in the specific technical discipline for which the assessor will perform on-site assessments (to be obtained within four years)
  - completion of four assessments under the supervision of a qualified assessor

  The first two items are covered by the basic assessor training course. The third and fourth items are stand alone items. A commenter suggested that the two-year/four-year time frame is too "loose" and suggested a move to a one-year/two-year time frame. The committee declined to make this change.

- Section 3.3.3 (Changes in Laboratory Capabilities) - There was considerable discussion of what constitutes "key personnel" or "major instrumentation," and of what is required of an Accrediting Authority in regard to a written response to a laboratory notification. The committee suggested that any personnel or instrumentation that would affect a laboratory's ability to perform analyses is "key" or "major," and that at a minimum the Accrediting Authority should document that it has evaluated the laboratory's notification of the change. Commenters suggested that the terms should be defined and that Accrediting Authorities and laboratories need explicit guidance in this area to ensure consistency among Accrediting Authorities. Noting that the issue also impacts the NELAC Accreditation Process (Chapter 4) and Quality Systems (Chapter 5) Standards, the committee tabled the issue to be addressed with those committees at a future date.

- Section 3.4.1.1 (Assessment Team) - It was suggested that an assessment team may include invited technical experts and/or support personnel. After considerable discussion of what constitutes a technical expert or support personnel, the committee approved additional language such that Section 3.4.1.1 will read as follows:

  > The Accrediting Authority determines the number and expertise of the assessors and support personnel that are required to conduct the on-site assessment based on the type of assessment and the scope of accreditation of the accredited or applicant laboratory. An assessment team may include technical support personnel approved by the Accrediting Authorities as capable of providing assistance to the assessors. These individuals need not be formally qualified by the Accrediting Authority as assessors (see 3.2.2). If not so qualified,

these individuals must still meet the requirements of the standards concerning conflict of interest and professional conduct. Members of the assessment team who provide technical assistance but are not qualified as assessors are not eligible to conduct interviews in the absence of the assessor nor to cite deficiencies. Although it is encouraged that teams directed by a lead assessor perform assessments, a single assessor knowledgeable in the discipline, methods, and regulations applicable to the laboratories he or she assesses can competently perform some on-site assessments.

- Section 3.4.2 (Scope of Assessment) - "The complete scope of accreditation" had been substituted for "all of the tests" in the committee's earlier discussion of the issues paper.

- Section 3.4.3 (Information Collection and Review) - A commenter asked if information review extends to secondary Accrediting Authorities such that a secondary Accrediting Authority may request information additional to that requested by the primary Accrediting Authority. It was noted that the NELAC Accrediting Authority Standard (Chapter 6) limits secondary Accrediting Authority review to their application only. The On-site Assessment Standard is not limiting at this time. Noting that the issue also impacts the NELAC Accrediting Authority Standard (Chapter 6) and Accrediting Authorities Standards, the committee tabled the issue to be addressed with those groups at a future date.

- Section 3.5.1 (Length of Assessment) - In response to a comment from the floor, the committee indicated that they will probably survey the Accrediting Authorities within the next six months to determine the average length of time and number of assessors used for NELAC assessments in order to evaluate whether additional language needs to be written for this section.

- Section 3.5.3 (On-site Laboratory Records Review and Collection) - Discussion once again turned to whether an assessor must review laboratory records for every laboratory test. Commenters did not want to risk an Accrediting Authority assessing for a partial scope of accreditation and accrediting for a complete scope of accreditation. The committee referred commenters to the change to Section 3..4.2 adopted earlier in the meeting in which "complete scope of accreditation" was substituted for "all of the tests." In addition, the committee referred participants to the issue paper presented earlier in the meeting and noted that the issue is on-going and will be revisited.

- Section 3.5.5 (Closing Conference) - It was suggested that this section implies that contested issues must be raised in the closing conference. This led to discussion of the appeals process available to laboratories that disagree with the results of their on-site assessment. After considerable discussion of the issue, the committee withdrew the proposed changes to the second paragraph of this section to take back to committee for discussion.

Since the committee's allotted session time was drawing to a close, Mr. Davis asked participants to identify critical issues that would preclude accepting the proposed changes to the Standard as written. Critical issues were identified as follows:

- Section 3.6.3 (Use of Checklists) - A commenter asked for clarification of "standardized checklists." The committee referred the commenter to the QS checklist and to technical checklists in use by Accrediting Authorities. The committee agreed that they need to better define what is meant by "standardized checklists" and indicated that they will discuss the issue further at a future date.

- Section 3.7.1 (Checklists) - A commenter suggested that the inclusion of a requirement that assessors reference laboratory procedures and record observations in support of "Yes" evaluations in addition to "No" evaluations for each audit checklist item is burdensome. In response, the committee agreed to streamline the language to remove references to "Yes" evaluations.

- Section 3.7.2 (Report Format) - A commenter suggested that this section gives the impression that deficiencies should be minimized in the assessment report. In response, the committee agreed to a minor language change, striking the sentence, "Deficiencies must be addressed at a minimum."

CONCLUSION

The committee's allotted meeting time having expired, Mr. Davis thanked participants for their input. He urged anyone noting a critical issue in the printed changes to be distributed prior to the closing plenary session that would preclude the acceptance of the changes to the Standard as written, to locate and inform a member of the committee. With that, the meeting was adjourned shortly after 5 p.m.

Attachment A

ACTION ITEMS
ON-SITE ASSESSMENT COMMITTEE MEETING
JUNE 27, 2000

Item No.	Action	Date to be Completed
1.	Committee to coordinate with NELAC Accreditation Process (Chapter 4) and Quality Systems (Chapter 5) Committees to offer clarification/guidance for Accrediting Authorities and laboratories regarding changes in laboratory capabilities. (See 3.3.3)	10/15/00
2.	Committee to coordinate with NELAC Accrediting Authority (Chapter 6) Committee and Accrediting Authorities regarding secondary Accrediting Authority information review (See 3.4.3)	10/15/00
3.	Committee to consider straw poll of Accrediting Authorities regarding average length of time and number of assessors used for NELAC assessments to evaluate whether additional language should be drafted for Section 3.5.1.	7/1/01
4.	Committee to clarify/define "standardized checklists" as referenced in Section 3.6.3.	10/15/00

Attachment B

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JUNE 27, 2000

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